

PRODUCT: 54 500-cc. flasks of *isotonic solution of three chlorides* and 12 1,000-cc. flasks of *isotonic solution of sodium chloride* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Sterile Ringer's Solution for Parenteral Use" and "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standard, since they were not substantially free of any turbidity and undissolved material, as required by the Pharmacopoeia, but were contaminated with undissolved material.

DISPOSITION: November 8, 1948. Default decree of condemnation. The products were ordered delivered to the Food and Drug Administration, for official purposes.

2520. Adulteration of solution of sodium chloride. U. S. v. 6 Cases * * *. (F. D. C. No. 25345. Sample No. 9385-K.)

LIBEL FILED: August 6, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about April 27, 1948, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 6 cases, each containing 12 flasks, of solution of *sodium chloride* at New York, N. Y. The product was intended for intravenous injection, as evidenced by the statement on the flask label "For the purpose of filling and rinsing the tubing this unit contains 50 cc. in excess of the declared volume."

LABEL, IN PART: "Sodium Chloride 5% in Distilled Water 500 cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it contained undissolved material, whereas an article which is represented for intravenous use should be substantially free of any undissolved material.

DISPOSITION: August 27, 1948. Default decree of condemnation and destruction.

2521. Adulteration and misbranding of A-C-D anticoagulant acid citrate dextrose. U. S. v. 18 Flasks * * *. (F. D. C. No. 25346. Sample No. 10602-K.)

LIBEL FILED: August 5, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about June 18, 1947, by the Continental Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 18 55-cc. flasks of *A-C-D anticoagulant acid citrate dextrose* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Anticoagulant Acid Citrate Dextrose," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality fell below the official standard since it was pyrogenic and contaminated with undissolved material.

Misbranding, Section 502 (a), the label statement "This product is * * * non-pyrogenic" was false and misleading as applied to this article, which contained pyrogen.

DISPOSITION: November 8, 1948. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for official purposes.

2522. Adulteration of ampuls of sodium iodide. U. S. v. 11,940 * * * Ampuls etc. (F. D. C. No. 25085. Sample Nos. 10575-K to 10578-K, incl.)

LIBEL FILED: July 13, 1948, Eastern District of New York.

ALLEGED SHIPMENT: On or about April 21, 1948, by the Veterans Administration Supply Depot, from Broadview, Ill. This was a return shipment.

PRODUCT: 11,940 20-cc. ampuls and 33,075 10-cc. *ampuls of sodium iodide* at Long Island City, N. Y.

LABEL, IN PART: "20 cc. + Ampule Sodium Iodide 10% W/V Intravenous," or "10 cc. Ampul Sodium Iodide 2 grams for Intravenous Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 28, 1948. Default decree of condemnation and destruction.

2523. Adulteration and misbranding of estrogenic hormone. U. S. v. 1 Bottle * * * (F. D. C. No. 24328. Sample No. 18025-K.)

LIBEL FILED: February 10, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 18, 1947, by Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 1 bottle containing 3 liters of *estrogenic hormone* at Indianapolis, Ind. Examination showed that each cubic centimeter of the article contained 0.78 milligram of ketones calculated as estrone.

LABEL, IN PART: "Whole Natural Estrogenic Hormone in Propylene Glyco."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, i. e., "Whole Natural Estrogenic Hormone * * * consisting of estrone with small amounts of auxiliary hormones, each cc equivalent to 20,000 international unit of estrone. Minimum ketone content 90-95%."

Misbranding, Section 502 (a), the above-quoted label statement was false and misleading, since the article did not have the composition represented and implied thereby.

DISPOSITION: November 1, 1948. Default decree of forfeiture and destruction.

2524. Adulteration and misbranding of Aquadiol. U. S. v. 23 Vials * * * (F. D. C. No. 25124. Sample No. 255-K.)

LIBEL FILED: July 27, 1948, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 17, 1948, by the National Drug Co., from Atlanta, Ga.

PRODUCT: 23 vials of *Aquadiol* at Philadelphia, Pa. Examination showed that the product contained less than 0.13 milligram of alpha estradiol per cubic centimeter.

LABEL, IN PART: (Vial) "25 cc. Aquadiol * * * Estrogenic Hormone containing per cc. 0.22 mg. alpha Estradiol."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 0.22 milligram of alpha estradiol per cubic centimeter.

Misbranding, Section 502 (a), the label statement "per cc. 0.22 mg. alpha estradiol" was false and misleading.

DISPOSITION: September 14, 1948. Default decree of condemnation and destruction.

2525. Adulteration of phenobarbital tablets. U. S. v. 14 Drums * * * (F. D. C. No. 24846. Sample Nos. 18498-K, 18499-K, 18787-K, 18788-K.)

LIBEL FILED: May 21, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about February 27 and March 12, 1948, by Clark-Babbitt Pharmaceutical Labs., Inc., from Boston, Mass.

PRODUCT: *Phenobarbital tablets*. 8 drums containing a total of 400,000 tablets and 6 drums containing a total of about 388,525 tablets at Gallipolis, Ohio.

LABEL, IN PART: "C. T. Phenobarbital 1½ gr."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard, since a portion of the tablets contained less than the declared amount of phenobarbital and the remainder of the tablets contained more than the declared amount of phenobarbital. (The tablets in the 8-drum lot contained less than 80 percent of the declared amount of phenobarbital; the tablets in 1 drum of the 6-drum lot contained not more than 92 percent; and those in the remaining 5 drums contained more than 109 percent of the labeled amount of phenobarbital. The Pharmacopoeia requires that *phenobarbital tablets* contain not less than 94 percent, and not more than 106 percent, of the labeled amount of phenobarbital.)

DISPOSITION: July 29, 1948. Default decree of destruction.